HFI-35 773

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1123526

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

December 23, 1997

**WARNING LETTER**

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

Mr. Miguel A. Arrizon
Regulatory Affairs Manager
Pari Respiratory Equipment, Inc.
13800 Hull Street Road
Midlothian, Virginia 23112

Dear Mr. Arrizon:

During a Food and Drug Administration (FDA) inspection conducted on November 6, 7, 24 & 26 and December 4, 9 & 12, 1997, at your Midlothian, Virginia facility, it was determined that your firm manufactures ProNeb, DuraNeb 1000, DuraNeb 2000, et.al. compressors and nebulizers. The compressors and nebulizers are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, manufacturing, packing, storage, or installation, are not in conformance with Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulations, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practice (GMP) for Medical Device Regulations was superseded on June 1, 1997, by the Quality Systems Regulation. The deficiencies noted during the inspection are violations of both the CGMP and the 1978 GMP.

The deficiencies are as follows:

1. Failure to validate the finished device testing software for the ProNeb and DuraNeb 2000 compressors and complaint handling software according to established protocols.

2. Failure to establish written procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met.

3. Failure to establish written procedures and to develop specifications for the contract manufacture of the AC motors used in the manufacture of compressors.

4. Failure to establish written procedures for implementing corrective and preventive action.

5. Failure to establish adequate written procedures for receiving, reviewing, and evaluating complaints, and to follow such procedures.

6. Failure to follow written procedures to control products that do not conform to specified requirements, as you did not document finished device test failures and device serial numbers.

7. Failure to establish adequate final acceptance procedures specifying that all acceptance data and documentation be reviewed, signed, and dated by a designated individual(s) prior to release of the finished device.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 (enclosed) issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters concerning devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected, and no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt measures to correct these deviations. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence and to comply with our request. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,

William M. Ment

William M. Ment
Acting Director, Baltimore District

Enclosure

cc: Mr. Werner Gutmann, President
Pari-Weak GmbH
Moosstra Be
D-82319 Starnberg, Germany